



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,421	01/07/2002	Dave Parsons	CV-0290	3678

7590 03/31/2004

Bristol Myers Squibb Company
100 Headquarters Park Drive
Skillman, NJ 08558

EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,421

Applicant(s)

PARSONS ET AL.

Examiner

JOHN D PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 9-16 are pending in this application.

Applicant's election with traverse of the invention of Group I, claims 9-15, in the reply of 12/8/2003 is acknowledged. Applicant argues that sepsis in wounds is distinguishable from systemic sepsis. The Examiner maintains that the method of treating sepsis in a wound is distinct and lacks unity of invention from treating ordinary wounds. Sepsis is defined as the presence of various pus-forming and other pathogenic organisms or their toxins in the blood or tissues. A complication of sepsis is bacteremia, which leads to tissue and organ damage. While using a topical anti-infective agent such as iodine to protect against the likelihood of sepsis in wounds may be considered to have unity of invention, a method of *treating* sepsis (i.e. sepsis already developed) is another matter. For treating sepsis in wounds, separate considerations must be taken into account, in order to fully address the consequence of sepsis in wounds.

The contribution that the invention of Group I makes over the prior art is in the composition and method of treating wounds with an iodine preparation. The contribution that the invention of Group II makes over the prior art is in the treatment of sepsis in wounds. Therefore, there is no technical relationship among the two inventions involving one or more of the same or corresponding special technical features.

Art Unit: 1616

For these reasons, the claims lack unity of invention, and the lack of unity requirement set forth in the Office Action of 11/4/2003 is still deemed to be proper. Accordingly, claim 16 is withdrawn from further consideration by the Examiner as being directed to non-elected subject matter, and claims 1-15 will presently be examined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Winicov et al. (US 4,271,149).

Winicov et al. explicitly disclose a composition that contains 0.01-0.25% iodine, 0.05-0.5% iodide ion from any source, 0.05-0.1% iodate from any source, detergent or solvent, and buffering agent to maintain pH in the range of 5-7 (column 2, lines 43-54). Iodine is shown to be generated upon mixing iodate with iodide (column 2, lines 25-30). Table III discloses Composition B, which contains 1% iodine, 0.45% HI, 0.2% sodium iodate, citric acid + sodium hydroxide (which generates the citric acid/citrate buffer), and final pH of 5.6.

Claim feature: use on wounds

Winicov's composition is a germicidal composition, which is suitable for various uses such as handwashing or treating bovine mastitis (see claim 1; column 5, Example 2; column 6, Example 3; column 7, lines 61-67). Although the term "wound" does not explicitly appear in Winicov's disclosure, Winicov nonetheless discloses the same exact composition with the same exact ingredients. Therefore, because the composition is the same in ingredient makeup, the same property must necessarily be present in Winicov's composition. See MPEP 2112, 2112.01.

Claim feature: "characterized in that the iodide is held separately from the oxidant until the point of use"

Applicant's claim feature has two consequences. It is either directed to a pre-mix or a final mix. The Examiner maintains that the claims, when interpreted broadly as reasonable, are readable on the final mix. If it does not read on the final mix, applicant is invited to expressly state so for the record. The fact that the iodide is held separately does not change the fact that when it is mixed together, the final mixture results in the presence of iodine, iodide, oxidant, and buffer at the claimed pH. It is this fact that must be kept in mind when examining the claims. The above noted "held separately" feature does not change what the final mixture is. The final mixture is explicitly disclosed by Winicov et al.

Claim feature: "capable of generating from 5 μg of iodine per g of composition per hour to 1500 μg of iodine per g of composition per hour"
or "100 μg of iodine per g of composition per hour"

Winicov's composition contains 0.01-0.25% I_2 + 0.05-0.5% iodide + 0.05-0.1% iodate. Winicov's formula shows that it takes 5 molar amount of the iodide to react with one molar amount of the iodate to produce 3 molar amount of I_2 (see the formula on column 2, line 29). At the maximum amount of iodate, 0.1 g iodate/100 g of composition, 0.00057 mole of iodate is present. As there is excess iodide when using 0.5% iodide, all of the iodate is **capable** of reacting with the iodide to generate iodine. When all of the iodate reacts, 0.00171 mole iodine is generated per 100 g of the composition, which is equal to 4340 μg of iodine per 1 g of the composition. Note however that Winicov et al. explicitly disclose the low range of iodate, which is 0.05% iodate. This is 20 times less than the figure calculated above. Hence, 217 μg iodine generation is expressly disclosed also. 100 μg would result from a reduction of either iodate or iodide therefrom, which reduction in amounts is clearly encompassed by the ranges taught by Winicov et al. As for the "per hour" limitation, this is a rate of reaction factor that is governed by any number of factors such as depletion of ionic species or iodine, or quantity of water, or pH of the medium. Keeping in mind that applicant's claims require being "capable of generating" the claimed iodine amounts and rates, Winicov's disclosure clearly and explicitly disclose such "capable" compositions.

For these reasons, the claims are anticipated.

Claims 9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bentley et al. (US 5,128,136).

Bentley et al. explicitly disclose a wound healing kit that contains in three separate containers (i) collagen and a pH buffer, (ii) iodide and oxidizing agent, and (iii) iodate. See claim 6. The buffer is in the range of 5.5 to 7.5 (column 6, lines 50-53). See also column 5, line 65 to column 6, line 68.

Bentley et al. keep the iodide separate from the oxidizing iodate (applicant's exemplified oxidant). Even though the iodide is held together with a different oxidizing agent, the literal claim language appears to be met. Alternatively, the explanation given above regarding the claims being readable on the final mixture of ingredients is applicable here also. Applicant's claims are readable on the final mixed-composition, and Bentley et al. clearly teach mixing the ingredients to deliver wound treatment. The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winicov et al. in view of Bentley et al.

The discussion of the teachings of Winicov et al. as set forth above is incorporated herein by reference.

Bentley et al. teach that the iodide + iodate iodine generating system is suitable for treating wounds (see column 5, lines 32-37; the paragraph bridging columns 5 and 6; and claim 6).

Upon further review and reconsideration, it is determined that Winicov et al. do not *expressly* disclose formulation to generate 5-1500 μg iodine per gram of the composition per hour over a period of three days (see applicant's claim 12). However, at least in the low end of that range, it has been shown in this Office action that Winicov's disclosure encompasses generating up to 868 times 5 μg ($4340/5 = 868$). Therefore, Winicov's composition clearly has the reservoir of reactants to produce 5 μg iodine per hour for a period of three days. Again, the ordinary skilled artisan would have recognized that the rate of reaction and quantity of iodine generated are controlled by iodine demand/depletion, and the equilibrium factors of the components (see the equation on column 2, lines 29).

While Winicov et al. do not expressly disclose wound treatment in verbatim language, handwashing and teat treatment for mastitis are disclosed. Further, any person having ordinary skill in the art would have recognized iodine composition as

being suitable for wound treatment. The disclosure by Bentley et al. is supportive of this position.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the combined teachings of the cited references.

For these reasons, all claims must be refused again.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**, **effective February 3, 2004**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Thurman Page, can be reached on (571)272-0602, effective February 3, 2004.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.



JOHN PAK
PRIMARY EXAMINER
GROUP 1000